510(k) Summary
as required by 807.92

K082663

OCT 0 6 2008

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan-shi, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager of Product Safety

3. Date of Submission

September 11, 2008

4. Device Trade name

Color LCD Monitor, RadiForce RS110

5. Common/Usual Name

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	Color LCD Monitor
Model Name	:	RadiForce R12
510(k) No.	:	K040982

8. Description of Device

RadiForce RS110 is a 48cm (19") Color LCD display for medical image viewing. RS110 displays high-definition medical imaging.

9. Intended Use

RadiForce RS110 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. RadiForce RS110 does not support the display of mammography images for diagnosis.

10. Technological Characteristics

RadiForce R12 is substantially equivalent to RS110. RS110 employs the maximum resolution values same as that of R12. RS110 improved the brightness, contrast and viewing angle of the LCD module, and modified the calibration software. The brightness improved in 290 cd/m2 from 270cd/m2. The contrast improved by it.

Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1.

Appendix 1: Comparison Table with Predicate Device

Items	R12	RS110
510(k) Number	K040982	Not Known
Panel Size and Type	48cm (19")	Same as R12
Pixel Pitch	0.294 mm x 0.294 mm	Same as R12
Available Cabinet Colors	Black	Same as R12
Display Colors	16.77 million from a palette of 1.06 billion colors	Same as R12
Viewing Angles	H: 170°, V: 170°	H: 176°, V: 176°
Scanning Frequency (H, V)	Digital: 30-65kHz 59-61Hz (VGA Text:65-71Hz) Analog: 30-82kHz 49-86Hz (1280 x 1024 : 49-76Hz) Frame synchronous mode: 57.5-62Hz	Same as R12
Native Resolutions	1280 × 1024	Same as R12
Brightness	270 cd/m^2	290 cd/m^2
Contrast Ratio	450 : 1 (typical)	800 : 1 (typical)
DOT Clock	Digital 108 MHz, Analog: 135 MHz	Same as R12
Response Time	20 ms (typical)	25 ms (typical)
Input Signals	Digital: DVI Standard 1.0, Analog: RGB Analog	Same as R12
Input Terminals	DVI-D 29 pin x 2	D-Sub mini 15pin, DVI-I 29pin (swichable)
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	Same as R12
Active Display Size (H x V)	376.3 mm x 301.0 mm	Same as R12
Viewable Image Size	481 mm (diagonal)	Same as R12
Luminance Calibration	Software (Optional) Photo-sensor (Optional)	Same as R12
Power	AC100-120V/200-240V, 50/60Hz	Same as R12
Power Management	DVI-DMPM VESA DMPM	Same as R12
Power Consumption	60 watts (typical)	55 watts
Power Save Mode	Less than 8 watts	Less than 1.3 watts
Dimensions (W x H x D)	With Stand: 414 x 409.5 – 509.5 x 203 mm Without Stand: 414 x 340 x 64 mm	Same as R12
NET Weight	With Stand: 8.1 kg Without Stand: 5.8 kg	With Stand: 7.6 kg Without Stand: 5.3 kg
Certifications & Standards	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), FCC-B, Canadian ICES-003-B, VCCI-B, EIZO ECO Products 2002	CE (Medical Device Directive), TUV/GM (EN60601-1), cTUVus (UL 60601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-B, c-Tick, EPA ENAERGY STAR®, EIZO Products 2009, RoHs

*The software used in RS110 is modified, refer to the "12. Information of Software used in RS110".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 6 2008

Mr. Hiroaki Hashimoto
Manager
EIZO NANAO Corporation
Product Safety
153 Shimokashiwano-cho
Hakusan, Ishikawa-ken, 924-8566
JAPAN

Re: K082663
Trade/Device Name: Color LCD Monitor, RadiForce RS110
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 11, 2008
Received: September 12, 2008

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K082663

Device Name : Color LCD Monitor, RadiForce RS110

Indications for Use:

RadiForce RS110 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. RadiForce RS110 does not support the display of mammography images for diagnosis.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082663